REMARKS / DECLARATION FILED

Claims 22 and 29-33 are pending in the application. Claims 1-21 and 23-28 have been cancelled. Previously presented claims 22, 29, 32, and 33 have been amended. No new matter has been added.

Applicants respectfully request allowance of the pending claims in view of the remarks and previously presented inventor's declaration filed under 37 C.F.R. § 1.132 ("Berghof-Jaeger Declaration").

Claim Rejections – 35 U.S.C. § 112

Claims 29, 31, and 33 were rejected under 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserted that the specification has not provided an alignment of the chromosomes of the different *Salmonella enterica* subspecies recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of *Salmonella enterica* subspecies recited. Additionally, the Examiner believed that the specification would provide insufficient guidance regarding what sequences from the different strains of salmonella could be used to construct appropriate primer or probe sequences.

For the following reasons, the Applicants respectfully deem the Examiner's arguments to be inappropriate. First, the specification provides sufficient information that allows a person skilled in the art to "visualize or recognize the identity of the members of the genus." Specifically, page 4, paragraph 56 of the published application, Pub. No. US 2004/0142350 ("the '350 application"), states:

> A comparison of the DNA sequences of all 37 Salmonella strains showed that while it was as a whole a conserved DNA region, the degree of conservation appeared at first glance to have only limited suitability for deriving Salmonella-specific oligonucleotides. Even in the most highly conserved regions, base substitutions were observed in some of the sequenced strains. Interestingly, it was found that many of the base substitutions occur only within a subgroup and that the substitutions are moreover generally conserved within that subgroup. This suggested the possibility of using more than two primers in the PCR in order to enable

> amplification also of those variants in which one or more base substitutions are present in the region of the primer binding sites. As the person skilled in the art will know, for that purpose there are customarily used degenerate primers or primers having deoxyinosin at the variable sites. A number of degenerate oligonucleotides that were potentially suitable as primers for the detection of all *Salmonella enterica* subspecies were therefore deduced from the above-mentioned sequence comparison. It was found, however, that those degenerate primers have only limited suitability for PCR detection since they result in an increase in the occurrence of non-specific reaction products, especially in the case of sequence regions of high complexity. Since the sensitivity of the PCR detection generally suffers from the occurrence of such non-specific reaction products, a different procedure was tried. "Complementing" primers were used in the PCR. In contrast to degenerate primers, in which all the possible combinations of the individual base substitutions are represented in the primer mixture (number of primers=$2^x \times 3^y \times 4^z$ where x, y and z are the number of positions at which two, three or four different bases are observed in the region of the primer binding site), in such complementing primers only the actually occurring sequences are present. The advantage over degenerate primers lies in the lesser complexity of the primer mixture according to the invention, as a result of which the probability that non-specific amplification products will be formed is markedly reduced. As has been shown in a number of experiments, this is especially advantageous in PCR detection using samples having a high content of "non-specific" DNA (DNA that does not come from bacteria to be detected) since, otherwise, the sensitivity of the detection may be radically reduced.

And continues in paragraph 58 on the same page:

> The DNA sequence comparison yielded a number of relatively short DNA regions that appeared to be potentially suitable for the strategy described (use of in total ≥ 3 primers in the PCR) for optimising the Salmonella detection process.

Thus, the specification teaches and describes an alignment of the different salmonella species recited.

Second, the specification discloses several particular sequence sections for which it has been shown that they are suitable for detecting all of the salmonella strains of the seven subspecies. This is also reflected in the claim language, as the claim language requires that the claimed sequences contain portions of the recited particular isolated nucleic acid molecules.

Accordingly, it is the position of the Applicants that the instant specification does provide sufficient guidance for a person skilled in the art to determine appropriate regions of variability from which to construct appropriate sequences.

More particularly, using the alignment (i.e., comparison of the DNA sequences of all 37 salmonella strains) and the explicitly disclosed sequences, the specification clearly describes the claimed invention in sufficient detail that one skilled in the art can clearly recognize the invention with all its claimed limitations. This applies the more as sequences are easily available from public databases and sequence alignments are readily prepared by computer programs. Many of those computer programs are even available free of charge on the Internet.

Therefore, it is the position of the Applicants that by preparing an alignment as taught in the specification and using the particular sequences of the instant invention as identifiers, one of ordinary skill in the art would be clearly able to distinguish members from non-members of the claimed genus.

From the above, Applicants provide that it follows that the Examiner's viewpoint appears unjustified, and Applicants respectfully request the Examiner to withdraw the written description rejection.

Response to Arguments and Declaration under 37 C.F.R. § 1.132

The Examiner noted that the written description rejection under 35 U.S.C. § 112, ¶1 could be overcome by removing the functional language "wherein the set is used . . ." from claim 22. Accordingly, the Applicants have amended claim 22, as suggested by the Examiner and further submit that this rejection should be withdrawn.

Indefiniteness Rejection Claim Rejections – 35 U.S.C. § 112

The Examiner rejected claims 29, 31, and 33 under 35 U.S.C. § 112, ¶2 as allegedly being indefinite where the metes and bounds of the claims are unclear because SEQ ID NOS 1-5 contain less than 250 nucleotides each, yet the claim appears to be directed to a sequence with a length from 10 to 250 nucleotides from SEQ ID NOS 1-5 or their complements. Accordingly, the Applicants have amended claim 29 to read as presented in its Supplemental Amendment—After Non-Final Rejection dated November 13, 2007. Amended claim 29 now encompasses the specific sequence ID NOS 1-5 or their complements and one or more nucleic acid molecules

from 10-250 nucleotides that need to be identical to the recited sequences in at least 10 contiguous nucleotides.

Applicants respectfully submit that the additional sequences are now clearly defined by their length and particular nucleotides contained in their sequences. Consequently, the Applicants request that the Examiner withdraw the rejection, because the meets and bounds of the claims should be clear.

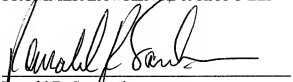
Double Patenting

Claims 22 and 29-33 were rejected on the ground of nonstatutory obvious-type patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,706,472. Applicants request that this rejection be held in abeyance until patentable claims have otherwise been allowed.

CONCLUSION

Reconsideration and withdrawal of the previous rejections and a prompt and favorable examination on the merits are respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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